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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/221,931      | 12/28/98    | TSURUGI              | T WAKAB37.001A      |

020995 HM12/0510  
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EXAMINER

BORIN, M

ART UNIT

PAPER NUMBER

1654

DATE MAILED:

05/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/221,931

Applicant(s)  
Tsuruo et al

Examiner  
M. Borin

Group Art Unit  
1654



☐ Responsive to communication(s) filed on \_\_\_\_\_

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-16 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-16 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

X Sequence Listing Letter

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **Part III DETAILED ACTION**

Claims 1-16 are currently pending.

Please see the attached NOTICETO COMPLY WITH SEQUENCE RULES which sets its own period for response.

It is noted that claims 13, 14 are in the "use" format, which is not proper according to US patent practice. For purposes of restriction these claims will be viewed as method of making claims.

#### **Restriction Requirement**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to catechin product, classified in class 514, subclass 456.
- II. Claims 11, drawn to method of inhibiting telomerase activity, classified in class 514, subclass 456.
- III. Claim 12, drawn to method of preventing or treating cancer, classified in class 514, subclass 456.
- IV. Claims 13-16, drawn to method of producing of pharmaceutical agent.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II/III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product

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as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case 1) the product as claimed can be used in other methods such as treatment of bacterial infections or treatment of skin conditions; 2) methods of use can be practiced with a broad variety of drugs beyond catechins, and 3) methods II and III are alternate methods of using the product of Group I.

Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case telomerase inhibitor, or anticancer agents can be prepared using active ingredients other than catechins, for example, benzo[b]thiophenes.

Inventions II and III are related as independent methods which are not connected in design, operation or effect. These methods are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the methods have different functions and different effect. A reference teaching method of treatment of cancer would not teach method of inhibiting telomerase activity and *vice versa*.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined. (MPEP 821.04)

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang can be reached on (703) 308-0254. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 5, 1999

mlb

MICHAEL BORIN, PH.D.  
PATENT EXAMINER





UNITED STATES DEPARTMENT OF COMMERCE  
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| EXAMINER      |              |
|---------------|--------------|
| Michael Borin |              |
| ART UNIT      | PAPER NUMBER |
| 1654          | 5            |

DATE MAILED:

Please find below a communication from the EXAMINER in charge of this application  
Commissioner of Patents

The communication filed on 1/15/99 is not fully responsive to the communication regarding the sequence Rules: see Notice to Comply.

Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within a time limit of one (1) month from the date of this letter.

NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 C.F.R. 1.136(a) OR (b), BUT THE STATUTORY PERIOD FOR RESPONSE SET IN THE COMMUNICATION MAILED [mail date] MAY BE EXTENDED UP TO A MAXIMUM OF SIX (6) MONTHS UNDER 37 CFR 1.136.

Any inquiry concerning this communication should be directed to Examiner M. BORIN, whose telephone number is (703) 305-4506.

MICHAEL BORIN, P.T.O.  
PATENT EXAMINER